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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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William Cork

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MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP  
300 S. WACKER DRIVE  
32ND FLOOR  
CHICAGO, IL 60606

EXAMINER

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/757,780	<b>Applicant(s)</b> CORK ET AL.	
	<b>Examiner</b> BJ Forman	<b>Art Unit</b> 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 15-25 and 39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-25 39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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## **FINAL ACTION**

### ***Status of the Claims***

1. This action is in response to papers filed 26 March 2007 in which claims 15-25 were amended, claims 1-14, 26-38 were canceled and claim 39 was added. All of the amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 26 September 2007, not reiterated below, are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection, necessitated by the amendments, are discussed.

Claims 15-25, 39 are under prosecution.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 15-25 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herron et al (WO 97/35181, published 25 September 1997) in view of Stimpson et

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al (U.S. Patent No. 5,599,668, issued 4 February 1997) and further in view of Strickland et al (U.S. Patent No. 5,576,827, issued 19 November 1996).

Regarding Claims 15 and 39, Herron et al disclose a method for detecting the presence of a target, the method comprising illuminating the light-receiving edge of a substrate to create total internal reflection, acquiring multiple images of the test spot and control/second spot (e.g. well patches comprising measurement well (152) and calibration well (154), page 14, line 31-page 15, line 25), acquiring multiple images taken at different exposures (pages 21-25) and determining the presence of target analyte complexes (page 23, line 24-page line 25, Fig. 3-4, 10-11). Herron et al teach the analyte complexes are labeled with tracer molecules (page 13, lines 24), but they do not specifically teach the labels are metallic nanoparticles. However, metallic nanoparticle labels were well known and routinely practiced in the art at the time the claimed invention was made as taught by Stimpson et al.

Stimpson et al disclose a similar method for detecting the presence of a target, the method comprising illuminating the light-receiving edge of a substrate to create total internal reflection, acquiring multiple images of the test spot and control/second spot (e.g. second situs, Column 11, line 33-Column 12, line 62), the multiple images taken at different exposures (i.e. different exposure times) and determining the presence of metallic nanoparticles (i.e. LSL, Column 16, lines 25-33) to determine presence of targets (Column 5, line 15-Column 6, line 42). Stimpson et al further teach the light scattering labels allows for precise detection of signal within a confined area thereby permitting simultaneous interrogation of the entire array and/or real-time measurement

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of binding and/or melting (Column 3, lines 45-55). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the light-scattering metallic labels of Stimpson et al. to the method of Herron et al. One of ordinary skill in the art would have been motivated to do so for the expected benefits taught by Stimpson i.e. the light scattering labels allows for precise detection of signal within a confined area thereby permitting simultaneous interrogation of the entire array and/or real-time measurement of binding and/or melting (Column 3, lines 45-55).

Both Herron and Stimpson practice the method using a laser light source and CCD detector (Herron, page 11, lines 6-10, page 12, lines 3-8; Stimpson, Column 11, lines 1-30). The references are silent regarding determination of an optimal exposure time.

However, optimizing exposure time using a laser and CCD optical system was well known and routinely practiced in the art at the time the claimed invention was made as taught by Strickland (Fig. 29, Column 9, lines 40-63; Column 20, lines 15-32; column 31, line 57-Column 32, line 55) who teaches the process characterizes the laser providing the means to correctly interpret data from the CCD (Column 27, lines 8-22).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the method step of determining optimal exposure time of the laser/CCD optical system as taught by Strickland to the laser/CCD optical systems of Herron and/or Stimpson. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success and for the well known

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benefit of characterizing the laser to thereby provide the means to correctly interpret data from the CCD (Strickland, Column 27, lines 8-22).

Regarding Claim 16, Herron et al teach the method wherein the control/second spot comprises a label conjugated to the substrate via a nucleic acid (page 13, lines 9-24, page 14, lines 7-10). Stimpson et al also teach the method wherein the substrate comprises multiple sites including positive, negative, calibration controls (Column 12, lines 28-31).

Regarding Claim 17, Herron et al teach the method wherein the analyte and capture probes are nucleic acids (page 14, lines 7-10). Stimpson et al teach the similar method wherein the test sample comprises a wildtype nucleic acid and the comparison comprises a mutant (i.e. single mismatch, Example 4-5). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the wildtype/mutant nucleic acids of Stimpson to the method of Herron. One of ordinary skill in the art would have been motivated to do so based on the well known clinical importance of mutations.

Regarding Claim 18, Herron et al teach the method wherein the substrate comprises a plurality of wells containing test and comparison spots (Fig. 3, page 14, line 31-page 15, line 25) and further determining an optimal exposure (page 22, lines 3-17), wherein the images are taken at an optimal exposure time and at least one that is less than optimal (page 23, line 24-page 24, line 25).

Regarding Claim 19, Herron et al teach the method wherein determining optimal exposure includes determining saturation (page 22, lines 3-17).

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Regarding Claim 20, Herron et al teach the method further comprising performing regression analysis of test spots (I vs T, Fig. 10-11), selecting optimal exposure time, determining intensity for optimal exposure and determining presence of analyte by comparing intensity of test spot with intensity of control spot (page 23-26).

Regarding Claim 21, Herron et al teach the method wherein the signal processing uses analog detectors and analog-digital converters (page 20, lines 24-32) but they are silent regarding pixel values. However, Stimpson et al teach the similar method wherein the analog-to-digital conversion assigns a numerical value to each pixel (Column 22, lines 5-19). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the pixel values known in the art as taught by Stimpson to the analog-digital conversion of Herron et al. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success based on the well known practice of doing so as taught by Stimpson (Column 22, lines 5-19).

Regarding Claim 22, Herron et al teach the method wherein selecting an optimal exposure comprises determines saturation (page 22, lines 3-17).

Regarding Claim 23, Herron et al teach the method wherein the step of determining intensity comprises extrapolation from generated signals (e.g. low control sample and high control sample, (page 23, lines 15-23). Stimpson et al teach the similar method wherein the data is interpolated (Example 2, Column 24, lines 35-53).

Regarding Claim 24, Herron et al teach the method wherein comparing intensity of the test spot includes performing statistical analysis to determine similarity to the

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control spot (page 23, line 15-page 24, line 25). Stimpson et al teach the similar method wherein the intensity is analyzed statistically (e.g. Example 2, Column 24, lines 35-53 and Example 5, Column 20, lines 46-58).

Regarding Claim 25, Herron et al teach the method wherein comparing intensity of the test spot includes performing statistical analysis to determine similarity to the control spot (page 23, line 15-page 24, line 25) but does not specifically teach means testing. However, Stimpson et al teach the similar method wherein the statistical analysis included means testing (Example 2, Column 24, lines 35-53 and Example 5, Column 20, lines 46-58).

### ***Double Patenting***

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).



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5. Claims 15-25 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 51 and 66 of U.S. Patent No. 11/530,138 (U.S. Patent Application Publication No. 2007/0148665). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to methods of detecting spots on the substrate wherein the spots comprising metallic nanoparticles. The claim sets merely differ in that the '138 claims define an additional step of compensating for distortion. However, the open claim language "comprising" as recited in the instant claims encompass the additional step of compensation recited in the '138 claims. Therefore, the claim sets are not patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### **Response to Comments**

6. Applicant has not traversed the above rejection, but requests that the rejection be held in abeyance until indication of allowable subject matter. The rejection is maintained and made FINAL.

7. Claims 15-25 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 51-67 of copending Application No. 11/530,110 (U.S. Patent Application Publication No. 2007/0041624). Although the conflicting claims are not identical, they are not patentably distinct from each other

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because both sets of claims are drawn to methods of detecting spots on the substrate wherein the spots comprising metallic nanoparticles, the method steps including steps multiple imagining at different exposures. The claim sets merely differ in that instant independent Claim 15 defines the different exposures as different time while dependent Claims 59 of the '110 application defines this elements. Therefore, the claim sets are not patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

8. No claim is allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BJ Forman  
Primary Examiner  
Art Unit 1634

/BJ Forman/  
Primary Examiner, Art Unit 1634